REMARKS

Claims 14-22 are pending in the present application for the Examiner's review and consideration. Claims 1-13 have been canceled without prejudice. Claims 14, 17-20 and 22 have been amended to more particularly point out and distinctly claim the invention. No new matter has been added by these amendments.

THE REJECTION UNDER 35 U.S.C. § 102(b)

Claims 14 and 17 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,719,197 to Kanios et al. ("Kanios") for the reasons set forth on pages 2-3 of the Office Action. Applicant respectfully traverses.

Kanios does not anticipate the present invention. The Kanios reference discloses compositions and methods for the topical administration of pharmaceutically active agents to a mammal in need thereof, in particular, anesthesia and local anesthetic agents (*See, e.g.*, Kanios, col. 1, lines 28-32). Kanios describes its compositions as "flexible, finite, bioadhesive composition[s] for topical application". (*See* Kanios, at col. 2, lines 21-23; col. 31, lines-64-65). The flexible, finite, bioadhesive compositions disclosed in Kanios include a pharmaceutically active agent, a pharmaceutically acceptable solvent, a plasticizer, a pharmaceutically acceptable bioadhesive carrier, and a cohesiveness increasing amount of clay. (*See* Kanios, at col. 2, lines 21-38).

The term "finite" as used in Kanios, refers to a substance that is non-spreading and retains its form, such as a patch, a dressing or a bandage. For instance, in referring to carriers as being finite, Kanios describes the finite carriers as "non-spreading substances which retain their form, *e.g.* patches, dressings and bandages". (*See* Kanios at col. 1, lines 57-62). Also, Kanios states that the carrier can be a "non-adhesive tape or other *finite* carrier". (*See* Kanios at col. 8, lines 57-60). In addition, in defining a "flexible, finite, pharmaceutically acceptable carrier", Kanios states that this term "is intended to mean a *solid*". (*See* Kanios at col. 9, lines 29-36).

In contrast, Kanios uses the term "non-finite" to refer to substances that are liquid or semi-liquids. In particular, Kanios refers to "non-finite or liquid or semi-liquid carriers such as gels, lotions, emulsions, creams, plasters or ointments." (*See* Kanios at col. 1, lines 57-60). Also, Kanios discloses that a non-finite carrier can be a "cream, gel, emulsion, lotion, salve, paste, plaster, ointment, or spray-solution". (*See* Kanios at col. 8, lines 60-65).

In view of this disclosure in Kanios, the flexible, finite compositions described in Kanios that are used for topical applications are solid or non-liquid substances. This is further supported by the fact that Kanios discloses adding clay to the final composition (*See*, Kanios at col. 2, lines 30-34.) Therefore, Kanios' finite or non-liquid compositions do not describe or suggest the present invention, which is a liquid buccal spray composition. In fact, by teaching that its composition is a finite substance or a non-liquid, Kanios teaches away from the presently claimed composition which is a liquid that is capable of being administered by spraying.

Furthermore, Kanios describes its composition as having a thickness when the composition is applied to tissue. In particular, Kanios states that " the anesthetic drug selected, the concentration and *thickness* and the duration of the application [of the composition] is determined based upon the anesthetic's ability to penetrate the tissue." (*See* Kanios at col. 6, lines 53-64). This disclosure that Kanios' composition when applied has a thickness further shows that the composition is a solid or non-liquid.

Moreover, it should be noted that Kanios does not disclose or suggest that its compositions are spray-solutions as the Examiner alleges in the Office Action. Kanios only uses the term spray-solution when referring to the carrier or intermediate mixture used to make the final, finite compositions. (*See e.g.* Kanios at col. 8, lines 57-67). Nowhere in this reference does Kanios refer to the final, finite composition, which is to be administered topically, as a spray-solution. That Kanios does not refer to its flexible, finite composition as a spray-solution is not surprising since Kanios discloses that its compositions are solids, not liquids that are capable of being sprayed.

Therefore, Kanios does not describe or suggest the liquid buccal spray composition of the presently claimed invention. By disclosing that its compositions are finite or solid compositions, Kanios teaches away from the presently claimed invention. Therefore, the rejection based on Kanios should be withdrawn.

THE REJECTION UNDER 35 U.S.C. § 103(a)

Claims 15-16 and 18-22 were rejected under 35 U.S.C. § 103(a) as being obvious over Kanios in view of U.S. Patent No. 5,364,616 to Singer et al. ("Singer") for the reasons set forth on pages 3-4 of the Office Action. Applicant respectfully traverses.

Singer discloses methods for preventing or treating gingivitis (inflammation of the gums) or periodontitis (inflammation of the tissues that support the teeth) comprising

topically administering to gingival tissue of the oral cavity a composition comprising a safe and effective amount of a selective histamine-2 receptor antagonist compound (*See, e.g.*, Singer, col. 2, lines 32-37 and col. 1, lines 16-17 and 26-27).

As discussed above, Kanios does not render the presently claimed invention obvious. Singer does not remedy the deficiencies in Kanios. The Examiner cites Singer for allegedly disclosing concentration ranges and examples of flavoring agents. The mere disclosure of concentration ranges and examples of flavoring agents does not overcome the deficiencies in Kanios, *i.e.*, that unlike the claimed invention, Kanios' flexible, finite compositions are solids or non-liquids. Moreover, even assuming for the sake of argument that Singer discloses compositions that are liquid, there is no motivation to combine the teachings of Kanios and Singer. More specifically, as noted above, Kanios discloses that its compositions, which are to be administered to tissue, are flexible, finite or solid compositions. One of ordinary skill in the art would not be motivated to combine Kanios, which is directed to solid or finite compositions, with Singer, even assuming it discloses liquid compositions, because solid compositions are clearly different from liquid compositions. Therefore, the rejection of the claims based on the combination of Kanios and Singer should be withdrawn.

DOUBLE PATENTING

Claims 20 was rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of United States Patent No. 6,676,931. In response, and without agreeing with the double patenting rejection, Applicant intends to submit an appropriate Terminal Disclaimer once the claims are indicated to be allowable in the present application but for a Terminal Disclaimer. In the meanwhile, Applicant request that the double patenting rejection be held in abeyance.

CONCLUSION

All claims are believed to be in condition for allowance. Should the Examiner not agree that all claims are allowable, Applicant respectfully invites the Examiner to contact the undersigned attorneys for Applicant to arrange for an interview to accelerate the allowance of the present application. No fee is believed to be due for this amendment. Should any fee be due, please charge the required fee to Jones Day Deposit Account No. 503013.

Respectfully submitted,

Date September 24, 2004

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Enclosures